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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,526	10/26/2001	Frederick H. Hausheer	X-0211	3276

7590 11/20/2003

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,526	HAUSHEER, FREDERICK H.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's Response filed September 12, 2003, Paper No. 5, is acknowledged. Claims 1-15 remain under consideration. No amendments to the claims were set forth in Paper No. 5.

In the last Office Action claims 1, 2, 4-6 and 8 were rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al., Lancet. It was asserted Plowman teaches the parenteral administration of mesna to provide radioprotection at a dose of 400 mg/kg. Further, claims 1 and 4 were rejected under 35 U.S.C. 102(b) as being anticipated by van den Broeke et al., J. Photochem. Photobiol. It was asserted van den Broeke teaches the administration of mesna for UV radiation protection.

No response is noted to either of these rejections of record. Accordingly, both rejections are maintained.

Claims 1-15 were rejected in the last Office Action under 35 U.S.C. 103, as being unpatentable over Plowman et al., Lancet, because Plowman teaches the parenteral administration of mesna to provide radioprotection at a dose of 400 mg/kg.

Applicant argues Plowman does not teach or suggest the administration of mesna as therapy for radiation exposure, but rather that mesna affords 10% radioprotection without having an idea as to an "effective amount" for purposes of therapy. As a second point, Applicant argues only mesna is mentioned and "similar sulphydryl-containing molecules" teaches nothing to one skilled in the art. Applicant's third point is that the reference does not teach the concept of therapy for radiation protection, but rather warns clinicians of the dangers of the presence of mesna at the time of total body irradiation. Applicant further argues waiting 12 hours after mesna

infusion is opposite the subject matter of instant claims 5-13 which are directed to prophylactic treatment.

All of Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 1-15 under 35 U.S.C. 103 is maintained. The achievement of radioprotection as disclosed by Plowman is directed to protection against the harmful effects of radiation wherein the mesna-treated group showed significantly improved survival. Thus the definition of "therapy ", the treatment of an illness, is met. No quantitative component of therapy is recited in instant claims 1 and 5. A 12 hour lapse in administration of mesna and a warning were suggested by Plowman to avoid an interference in the effect of total body radiation. However, one skilled in the radiology and pharmaceutical arts would have been motivated to administer mesna and similar sulphydryl-containing compounds as a therapy against the harmful effects of radiation in view of Plowman's teaching because sulphydryl-containing molecules of close structural similarity to sodium-2-mercatoethane sulphonate, such as N-acetylcysteine, are known in the prior art as radioprotectors. The determination of what constitutes "similar sulphydryl-containing molecules" is a parameter that would have been readily discernable by those skilled in the art. It would have been reasonable to expect a laboratory model in which mice were given intraperitoneal injections of 400 mg/kg, would serve as an appropriate mammalian system from which one skilled in the art, through no more than routine experimentation, would have been able to determine an optimal therapeutic range, dosing regimen and

other modes of administration (both parenteral and oral). The disclosed dosage, 400 mg/kg, is within the range required by instant claims 2 and 6.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 703-308-4703.

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

November 19, 2003

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER